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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/788,074	02/16/2001	Gokhan S. Hotamisligil	21509-044	4331

7590

07/08/2002

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EXAMINER

SCHMIDT, MARY M

ART UNIT	PAPER NUMBER
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1635

DATE MAILED: 07/08/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/788,074

Applicant(s)

HOTAMISLIGIL, GOKHAN S.

Examiner

Mary Schmidt

Art Unit

1635

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-16 and 18-24 is/are pending in the application.
- 4a) Of the above claim(s) 1-15 and 18-20 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 16 and 21-24 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 10.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

Art Unit: 1635

### **DETAILED ACTION**

1. Please note that the Examiner of Record has changed in the instant Application. Please address all future correspondence to Examiner Schmidt (see the concluding remarks below for information on how to reach the Examiner).

#### ***Election/Restriction***

2. Claims 1-15 and 18-20 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Election was made without traverse as indicated in the Official Action mailed 10/23/01.

3. This application contains claims 1-15 and 18-20, drawn to an invention nonelected with traverse in Paper No. 9, filed 4/23/02. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01. Applicant wrote on page 3 of the response that "claims 1-15 and 17-20 have been canceled" however, as directed on page 1 of the response, only claim 17 was actually canceled. Claims 1-15 and 18-20, drawn to the non-elected inventions, remain pending.

#### ***Information Disclosure Statement***

4. The information disclosure statement filed 5/3/02 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each U.S. and foreign patent; each publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed as follows: The reference CN, the "International Preliminary Search Report mailed on February 19,2002", specifically, the references cited within this search report, have not been considered.

Art Unit: 1635

Since the instant Application is not a continuation, or national stage entry, of International Application cited in the I.D.S., no copy of the cited references in the search report has been placed in the instant Application. See MPEP1893.03 (g) which waives the need to cite references in an I.D.S. citing a search report as a part of the entry of the national stage application and states that there is no need to cite the documents in a PTO-892 form in that case, but "otherwise, applicant must follow the procedure set forth in 37 CFR 1.97 and 1.98 in order to ensure that the examiner considers the documents cited in the international search report." Furthermore, the documents considered relevant ought to be individually listed in the instant I.D.S. since the search report as cited in reference CN does not even list the PCT serial number, which is PCT/US01/05019. If the I.D.S. was published in a patent, the reference would not be complete.

***Priority***

5. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 119(e) as follows:

An application in which the benefits of an earlier application are desired must contain a specific reference to the prior application(s) in the first sentence of the specification or in an application data sheet (37 CFR 1.78(a)(2) and (a)(5)). Specifically, the first line of the specification does not reference priority to the provisional application, 60/183,106.

Art Unit: 1635

*Specification*

6. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed. Specifically, the title "Inhibition of MAL1" is not considered descriptive since the pending claims, claims 16 and 21-24 are drawn to methods of diagnosing a risk of developing insulin resistance via determining the levels of MAL1, and not methods of inhibiting MAL1.

*Claim Rejections - 35 USC § 112*

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 16 and 21-24 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 16 is drawn to a method of diagnosing a risk of developing insulin resistance in a mammal, comprising determining the level of Mal1 transcripts or polypeptide in a tissue sample, wherein an increase in the level of said transcripts or said polypeptide in said tissue compared to a normal control tissue indicates that said mammal is at risk of developing insulin resistance.

Art Unit: 1635

Claims 21-24 specify wherein the increase is 5%, 10%, 20% or 50% more than a normal control value.

The claims as written read on a broad scope of Mal 1 transcripts or polypeptides from any organism. The specification as filed teaches the sequence of human and mouse Mal 1 on pages 2 and 3. This disclosure does not provide a representative number of species of Mal 1 from any organism as broadly claimed so that one of skill in the art would have recognized that Applicant was in possession of the breadth of methods claimed for detection of any such Mal1.

**MPEP 2163** teaches the following conditions for the analysis of the claimed invention at the time the invention was made in view of the teachings of the specification and level of skill in the art at the time the invention was made:

**The claimed invention as a whole may not be adequately described where an invention is described solely in terms of a method of its making coupled with its function and there is no described or art-recognized correlation or relationship between the structure of the invention and its function. A biomolecule sequence described only by a functional characteristic, without any known or disclosed correlation between that function and the structure of the sequence, normally is not a sufficient identifying characteristic for written description purposes, even when accompanied by a method of obtaining the claimed sequence....A lack of written description issue also arises if the knowledge and level of skill in the art would not permit one skilled in the art to immediately envisage the product claimed from the disclosed process....Generally, there is an inverse correlation between the level of skill and knowledge in the art and the specificity of disclosure necessary to satisfy the written description requirement....The written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice..., reduction to drawings..., or by disclosure of relevant, identifying characteristics, i.e., structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying**

Art Unit: 1635

**characteristics, sufficient to show the applicant was in possession of the claimed genus.**

Since relevant identifying characteristics have not been provided for detection of Mal1 in other organisms, and as such, one skilled in the art would not have been able to readily envisage the sequence of Mal 1 from organisms other than human or mouse, the claims lack written description for the breadth of the claims to methods of detection of Mal1 from any organism.

9. The closest prior art cited of record did not teach the nexus between Mal1 expression and insulin resistance as instantly claimed, nor the motivation to determine Mal1 levels for diagnosing a risk of developing insulin resistance. The specification as filed taught by way of example Mal1 deficient mice which showed increased insulin susceptibility. This nexus was not previously taught in the prior art. As such, claims 16 and 21-24 as amended are found free of the prior art and enabled for diagnosing a risk of developing insulin resistance in a mammal via measuring the level of Mal1 in a tissue sample as claimed.


Art Unit: 1635

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to *Mary M. Schmidt*, whose telephone number is (703) 308-4471.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, *John LeGuyader*, may be reached at (703) 308-0447.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group Analyst, *Kay Pinkney*, whose telephone number is (703) 305-3553.

M. M. Schmidt  
July 1, 2002



JOHN L. LeGUYADER  
SUPERVISORY PATENT EXAMINER  
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